§ 900.11 Requirements for certification.

(a) *General.* After October 1, 1994, a certificate issued by FDA will be required for lawful operation of all facilities. In order to obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an accrediting body approved by FDA. On request from a facility, FDA will provide such facility with a current list of approved accrediting bodies. Any request for such list shall include the name and address of the facility and must be sent to the address provided in § 900.3(b).

(b) *Application*—(1) *Certificates.* When applying for accreditation to an approved accrediting body, a facility shall submit to such accrediting body the information required in 42 U.S.C. 263b(d)(1). If and when the facility becomes accredited, information required for certification of the facility shall be forwarded to FDA by the accrediting body, in accordance with § 900.4(g)(4).

(2) *Provisional certificates.* Facilities that have not obtained a certificate by October 1, 1994, but have applied for accreditation to an approved accrediting body by then are eligible to receive a provisional certificate. To receive a provisional certificate, a facility shall submit the information required in 42 U.S.C. 263b(c)(2) to an approved accrediting body. New facilities may also submit such information directly to FDA. If and when the accrediting body determines that such application is sufficiently complete for review purposes, this fact shall be communicated to FDA by the accrediting body in accordance with § 900.4(g)(5). To apply for a 90-day extension to a provisional certificate, a facility shall submit to the accrediting body a statement of what the facility is doing to obtain certification and evidence that a significant adverse impact on the regional availability of mammography would result if such facility did not obtain an extension. Such information shall be forwarded to FDA by the accrediting body in accordance with § 900.4(g)(5).

(c) *Issuance and renewal of certificates*—(1) *Certificates.* FDA will issue a certificate to a facility within 30 days of receipt of notification from an approved accrediting body of the accreditation of such facility. The initial certificate for a facility shall remain in effect until 30 days after the date of expiration of the facility's existing accreditation unless certification and/or accreditation of the facility is revoked prior to such deadline. FDA will issue a renewed certificate to a previously certified facility within 30 days of receipt of notification from an approved accrediting body of renewal of the accreditation of such facility. A renewed certificate shall be effective for a period of 3 years from the date of issuance, unless certification and/or accreditation of the facility is revoked prior to such deadline.

(2) *Provisional certificates.* FDA will issue a provisional certificate to a facility within 10 days of receipt of notification from an approved accrediting body of satisfaction of the requirements of paragraph (b)(2) of this section. A provisional certificate shall be effective for 6 months from the date of issuance. FDA will issue a 90-day extension for a provisional certificate within 10 days of receipt from the accrediting body of the information required in paragraph (b)(2) of this section, provided that FDA determines that the statutory prerequisites for the extension as set forth in section 354(c)(2) of the Public Health Service Act have been met. No renewal of a provisional certificate beyond the 90-day extension can occur.

§ 900.12 Quality standards.

The following requirements establish the minimum quality standards that must be met by a facility to be eligible for certification to provide screening and/or diagnostic mammography services:

(a) *Personnel.* The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities. Lists of personnel certifying bodies approved by FDA and referenced in this section may be obtained by submitting to FDA at the address specified in § 900.3(b) a request containing the information needed and the name and address of the facility.